

## 510(k) SUMMARY

(in accordance with 21 CFR 807.87(b) and 21 CFR 807.92)

# AVO Cream Topical Emulsion

### 1. Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

RRI Group, Inc.  
248 Latitude Lane, Suite 104  
Lake Wylie, SC 29710

Phone: (803) 831-7657  
Fax: (803) 831-1494

Contact Person: Lara Noah  
lnoah@rriint.com

Date Prepared: May 26, 2011

### 2. Name of Device and Name/Address of Sponsor

## AVO Cream Topical Emulsion

Trigen Laboratories, Inc.  
2400 Main Street Ext., Suite 6  
Sayreville, NJ 08872

#### Common or Usual Name

Dressing, Wound & Burn, Hydrogel w/drug biologic

#### Classification Name

Device	Unclassified
Review Panel	General & Plastic Surgery
Product Code	MGQ
Unclassified Reason	Pre-Amendment
Submission Type	510(k)

### 3. Substantial Equivalent Devices:

Trigen Laboratories Inc. believes that AVO Cream Topical Emulsion is substantially equivalent to the currently marketed device, Biafine® Wound Dressing Emulsion (Radiodermatitis Emulsion) cleared under K964240.

4. Device Description:

AVO Cream Topical Emulsion is a water-based emulsion formulated for the dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, 1st and 2nd degree burns, including sunburns, and radiation dermatitis. When applied properly to a wound, AVO Cream Topical Emulsion provides an optimum moist environment for the healing process and isolates the wound from harmful germs and other external contamination.

5. Intended Use Indications for Use:

AVO Cream Topical Emulsion is indicated for use in:

- Full Thickness Wounds, Pressure Sores, Dermal Ulcers including Lower Leg Ulcers
- Superficial Wounds
- 1st and 2nd Degree Burns, including Sunburns
- Dermal Donor and Graft Site Management
- Radiation Dermatitis

6. Summary of the Technological Characteristics of the Device Compared to the Predicate Device(s):

All products referenced are non-sterile emulsions that are applied topically to relieve the symptoms of various dermatoses.

7. Conclusions:

Functional and performance testing has been conducted to assess the safety and efficacy of AVO Cream Topical Emulsion and the results are satisfactory.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Trigen Laboratories, Inc.  
% RRI Group, Inc.  
Ms. Lara Noah  
248 Latitutde Lane, Suite 104  
Lake Wylie, South Carolina 29710-1457

NOV 18 2011

Re: K110762  
Trade/Device Name: AVO Cream Topical Emulsion  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: October 17, 2011  
Received: October 18, 2011

Dear Ms. Noah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K110762

Device Name: AVO Cream Topical Emulsion

Indications For Use:

AVO Cream Topical Emulsion is indicated for use in:

- Full thickness wounds, pressure sores, dermal ulcers including lower leg ulcers
- Superficial wounds
- 1<sup>st</sup> and 2<sup>nd</sup> degree burns, including sunburns
- Dermal donor and graft site management
- Radiation dermatitis
- Minor abrasions

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

\_\_\_\_\_  
Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) \_\_\_\_\_

David Krause for MKM  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K110762